W- 100 mm L-280 mm

Amodis® 500 IV

Metronidazole 0.5% w/v

COMPOSITION
Amodis® 500 IV: Each 100 ml solution contains Metronidazole BP 500 mg.

PHARMACOLOGY
Metronidazole is an antibacterial and antiprotozoal agent. Metronidazole is very active against the clinically important protozoa- *Trichomonas vaginalis, Giardia lamblia* & *Entamoeba histolytica* and anaerobic bacteria- *Bacteroides fragilis* & related species, *Fusobacterium, Clostridium, Peptococcus, Peptostreptococcus, Gardnerella vaginalis* and *Camphylobactor sp*.

INDICATION
Amodis® 500 IV is indicated in the prophylaxis and treatment of infections in which anaerobic bacteria have been identified. It is indicated in:
1. The prevention of postoperative infections due to anaerobic bacteria
2. The treatment of septicaemia, bacteraemia, peritonitis, brain abscess, necrotizing pneumonia, osteomyelitis, puerperal sepsis, pelvic abscess, pelvic cellulitis, and post operative wound infections from which pathogenic anaerobes have been isolated.

DOSAGE AND ADMINISTRATION
Amodis® 500 IV should be infused intravenously at an approximate rate of 5 ml/min. Oral medication should be substituted as soon as feasible. Treatment for 7 days should be satisfactory for most patients, but the physician might decide to prolong treatment.
For bacterial infections:
Adults: 500 mg (100 ml) 8 hourly.
Children: 7.5 mg/kg (1.5 ml/kg) 8 hourly.
For treatment before and during surgery:
Adults: 500 mg (100 ml) shortly before operation, repeated 8 hourly.
Children: 7.5 mg/kg (1.5 ml/kg) 8 hourly.

USE IN PREGNANCY AND LACTATION
Studies have not been done in humans. Metronidazole has not been shown to cause birth defects in animal studies; however, use is not recommended during the first trimester of pregnancy. Use is not recommended in nursing mothers since Metronidazole passes into the breast milk.

SIDE EFFECT
Pain, tenderness, redness or swelling over vein in which the medicine is given. Other side effects are unsteadiness, fever or chills, sore throat, headache, numbness, tingling pain or weakness in the hands or feet, pain, seizures, skin itching, unusual tiredness or weakness, vaginal irritation or discharge.

CONTRAINDICATION
Metronidazole is contraindicated in patients with a history of hypersensitivity to Metronidazole or other nitroimidazole derivatives.

DRUG INTERACTION
Metronidazole shows drug interaction with the following: alcohol or alcohol-containing beverages, barbiturates, carbamazepin, cimetidine, disulfiram, fluorouracil, lithium, methadone, phenytoin, warfarin etc.

PRECAUTION
Metronodazole should be given with caution in the following conditions- anaemia or other blood disorders, liver disease, disease of nervous system, seizures etc.

INSTRUCTION FOR THE USE OF Amodis® 500 IV
1. Check the bag for minute leaks by squeezing the inner bag firmly. If leaks are found, or if seal is not intact, discard the solution.
2. Do not use if the solution is cloudy or a precipitate is present.
3. Do not use flexible bags in series connections.
4. Close flow control clamp of administration set.
5. Remove cover from port at bottom of bag.
6. Insert piercing pin of administration set into port with a twisting motion until the pin is firmly seated.
7. Suspend bag from hanger.
8. Squeeze and release drip chamber to establish proper fluid level in chamber during infusion of **Amodis**® 500 IV.
9. Open flow control clamp to expel air from set. Close clamp.
10. Regulate rate of administration with flow control clamp.

STORAGE
Store below 25° C and protect from light. Avoid extreme heat and freezing. Keep out of reach of children.

HOW SUPPLIED
Amodis® 500 IV: Each box contains 1 bag of 100 ml solution of Metronidazole for intravenous infusion.

LFT0161

Manufactured by :
SQUARE
PHARMACEUTICALS LTD.
BANGLADESH